

## Public Health Service, HHS

## § 93.411

components, including, but not limited to ORI, the Office of Inspector General, the PHS funding component, and the debarring official.

### **§ 93.408 Mitigating and aggravating factors in HHS administrative actions.**

The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, and conserve public funds. HHS considers aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. HHS may consider other factors as appropriate in each case. The existence or nonexistence of any factor is not determinative:

(a) *Knowing, intentional, or reckless.* Were the respondent's actions knowing or intentional or was the conduct reckless?

(b) *Pattern.* Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?

(c) *Impact.* Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?

(d) *Acceptance of responsibility.* Has the respondent accepted responsibility for the misconduct by—

- (1) Admitting the conduct;
- (2) Cooperating with the research misconduct proceedings;
- (3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and

(4) Taking steps to correct or prevent the recurrence of the research misconduct.

(e) *Failure to accept responsibility.* Does the respondent blame others rather than accepting responsibility for the actions?

(f) *Retaliation.* Did the respondent retaliate against complainants, witnesses, committee members, or other persons?

(g) *Present responsibility.* Is the respondent presently responsible to conduct PHS supported research?

(h) *Other factors.* Other factors appropriate to the circumstances of a particular case.

### **§ 93.409 Settlement of research misconduct proceedings.**

(a) HHS may settle a research misconduct proceeding at any time it concludes that settlement is in the best interests of the Federal government and the public health or welfare.

(b) Settlement agreements are publicly available, regardless of whether the ORI made a finding of research misconduct.

### **§ 93.410 Final HHS action with no settlement or finding of research misconduct.**

When the final HHS action does not result in a settlement or finding of research misconduct, ORI may:

(a) Provide written notice to the respondent, the relevant institution, the complainant, and HHS officials.

(b) Take any other actions authorized by law.

### **§ 93.411 Final HHS action with settlement or finding of research misconduct.**

When a final HHS action results in a settlement or research misconduct finding, ORI may:

(a) Provide final notification of any research misconduct findings and HHS administrative actions to the respondent, the relevant institution, the complainant, and HHS officials. The debarring official may provide a separate notice of final HHS action on any debarment or suspension actions.

(b) Identify publications which require correction or retraction and prepare and send a notice to the relevant journal.

(c) Publish notice of the research misconduct findings.

(d) Notify the respondent's current employer.

(e) Take any other actions authorized by law.

INSTITUTIONAL COMPLIANCE ISSUES

**§ 93.412 Making decisions on institutional noncompliance.**

(a) Institutions must foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research.

(b) ORI may decide that an institution is not compliant with this part if the institution shows a disregard for, or inability or unwillingness to implement and follow the requirements of this part and its assurance. In making this decision, ORI may consider, but is not limited to the following factors—

- (1) Failure to establish and comply with policies and procedures under this part;
- (2) Failure to respond appropriately when allegations of research misconduct arise;
- (3) Failure to report to ORI all investigations and findings of research misconduct under this part;
- (4) Failure to cooperate with ORI's review of research misconduct proceedings; or
- (5) Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.

**§ 93.413 HHS compliance actions.**

(a) An institution's failure to comply with its assurance and the requirements of this part may result in enforcement action against the institution.

(b) ORI may address institutional deficiencies through technical assistance if the deficiencies do not substantially affect compliance with this part.

(c) If an institution fails to comply with its assurance and the requirements of this part, HHS may take some or all of the following compliance actions:

- (1) Issue a letter of reprimand.
- (2) Direct that research misconduct proceedings be handled by HHS.
- (3) Place the institution on special review status.
- (4) Place information on the institutional noncompliance on the ORI Web site.

(5) Require the institution to take corrective actions.

(6) Require the institution to adopt and implement an institutional integrity agreement.

(7) Recommend that HHS debar or suspend the entity.

(8) Any other action appropriate to the circumstances.

(d) If the institution's actions constitute a substantial or recurrent failure to comply with this part, ORI may also revoke the institution's assurance under §§ 93.301 or 93.303.

(e) ORI may make public any findings of institutional noncompliance and HHS compliance actions.

DISCLOSURE OF INFORMATION

**§ 93.414 Notice.**

(a) ORI may disclose information to other persons for the purpose of providing or obtaining information about research misconduct as permitted under the Privacy Act, 5 U.S.C. 552a.

(b) ORI may publish a notice of final agency findings of research misconduct, settlements, and HHS administrative actions and release and withhold information as permitted by the Privacy Act and the Freedom of Information Act, 5 U.S.C. 552.

**Subpart E—Opportunity To Contest ORI Findings of Research Misconduct and HHS Administrative Actions**

GENERAL INFORMATION

**§ 93.500 General policy.**

(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and HHS administrative actions, including debarment or suspension, arising under 42 U.S.C. 289b in connection with PHS supported biomedical and behavioral research, research training, or activities related to that research or research training.

(b) A respondent has an opportunity to contest ORI research misconduct findings and HHS administrative actions under this part, including debarment or suspension, by requesting an